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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/667,483	09/23/2003	Takumi Kagawa	380-41	9078
23117 7	590 02/21/2006	EXAMINER		
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR			PERLINGER, SARAH E	
ARLINGTON, VA 22203			ART UNIT	PAPER NUMBER
,			1625	

DATE MAILED: 02/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

11		A C A' N -	A multipoption			
		Application No.	Applicant(s)			
		10/667,483	KAGAWA ET AL.			
	Office Action Summary	Examiner	Art Unit			
		Sarah E. Perlinger	1625			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠	Responsive to communication(s) filed on 20 L	December 2005.				
·		s action is non-final.				
, —	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is					
	closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4) 🖂	4)⊠ Claim(s) <u>1-30</u> is/are pending in the application.					
•	4a) Of the above claim(s) <u>1-8 and 12-30</u> is/are withdrawn from consideration.					
	5) Claim(s) is/are allowed.					
6)⊠	☑ Claim(s) <u>9-11</u> is/are rejected.					
	Claim(s) is/are objected to.					
8)	Claim(s) are subject to restriction and/o	or election requirement.				
Application Papers						
9) The specification is objected to by the Examiner.						
10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under 35 U.S.C. § 119						
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> </ul>						
* See the attached detailed Office action for a list of the certified copies not received.  Attachment(s)  1)  Notice of References Cited (PTO-892)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  * See the attached detailed Office action for a list of the certified copies not received.    Interview Summary (PTO-413)   Paper No(s)/Mail Date						
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  Paper No(s)/Mail Date  5) Notice of Informal Patent Application (PTO-152)  6) Other:						

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#### **DETAILED ACTION**

1. Applicant's election with traverse of group II in the reply filed on January 12, 2006 has been entered.

# 2. Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The specification lacks sufficient description in the claimed scope when "an optically active epoxyester derivative of formula (3)" is claimed. The specification merely describes (2S,3R)-stereoisomers of the optically active epoxyester derivatives of formula (3) (Specification, pages 16-17) and lacks description of any other stereoisomers of the optically active epoxyester derivatives of formula (3).

In the specification no examples of (2S,3S), (2R,3S) or (2R,3R) forms of the optically active epoxyester derivatives of formula (3) are disclosed. It is noted in the art that broadly such description as found in the claims, encompassed such structure as that found in EP 0362556 (claim 1) for which no description for such structure is disclosed but read on by the claims. The description of stereochemistry of the optically active epoxyester derivatives is particularly pertinent at the point of novelty over the art. The claims embraced optically active epoxyester

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stereoisomers of EP 0362556, however the description seen in the specification is limited to those found on pages 16-17. It is recommended that the particular stereoisomer of the optically active epoxyester derivative be explicitly delineated in the claims.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Corey et al. (*Tetrahedron Letters*, 1991, 32, 2858, Table I).

The reference disclosed the synthesis of the instant claimed  $\alpha,\beta$ -epoxy ester (compound 2, page 2858) from an  $\alpha$ -bromo  $\beta$ -hydroxy ester precursor (compound 1 of Table 1, page 2858). The disclosed reaction of the  $\alpha$ -bromo  $\beta$ -hydroxy ester precursor (wherein R=cyclohexyl) and Kot-Bu in t-BuOH enable the formation of the instant claimed  $\alpha,\beta$ -epoxy ester wherein R<sup>1</sup>=cyclohexyl and R<sup>2</sup>= t-butyl (compound 2, page 2858). The reference clearly delineated the claimed species in a very small genus, (only 6 R-groups in Table I of page 2858) therefore anticipation was found (see Ex Parte A 17 USPQ 2d 1716). Furthermore, the small  $\alpha,\beta$ -epoxy ester genus wherein R<sup>1</sup>=cyclic alkyl group and R<sup>2</sup>= t-butyl, is anticipated by the clear delineation of the synthesis of the  $\alpha,\beta$ -epoxy ester wherein R<sup>1</sup>=cyclohexyl and R<sup>2</sup>= t-butyl. The species within this small genus are structurally similar to the  $\alpha,\beta$ -epoxy ester (wherein R<sup>1</sup>=cyclohexyl). Therefore, the disclosure of the synthesis of this particular species provides description of all

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other species within the small genus (see *Tetrahedron Letters*, 1991, 32, 2858, Table I and paragraph 4, *Ex Parte A* 17 USPQ 2d 1716 and *In re Schaumann* 197 USPQ 5).

## 3. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baures et al.

(Tetrahedron Letters, 1990, 31, 6502) in view of Corey et al. (Tetrahedron Letters, 1991, 32, 2857-2860) and Corey et al. (Tetrahedron Letters, 1992, 33, 6735-6738).

### Determination of the scope and content of the prior art (MPEP§ 2141.01)

Baures et al. and both Corey et al. references disclose structurally similar compounds against the base claims as delineated.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

The difference between the species claims 9-11 and compounds 3a, 3c (Baures et al. *Tetrahedron Letters*, 1990, 31, 6501-6502, Table 1 and Table 2) is that instead of R<sup>1</sup> being a phenyl substituent, R<sup>1</sup> of the instant claimed species is a methyl, ethyl or a C<sub>3-10</sub> branched, linear or cyclic alkyl group and instead of R<sup>2</sup> being only a phenyl or a 4-methoxyphenyl, R<sup>2</sup> of the instant claimed species is a phenyl, substituted phenyl, tert-butyl or a 4-methoxyphenyl. Corey et al. discloses the base structure with an ethyl group as the R<sup>1</sup> substituent (*Tetrahedron Letters*, 1992, 33, 6735, Structure 3). Furthermore, Corey et al. discloses the base structure wherein R<sup>1</sup> is a cyclohexyl and R<sup>2</sup> is a tert-butyl (see *Tetrahedron Letters*, 1991, 32, 2858, Table I and paragraph 4 and *Ex Parte A* 17 USPQ 2d 1716).

#### Finding of prima facie obviousness-rationale and motivation (MPEP § 2142-2143)

One having ordinary skill in the art in possession of Baures et al. and both Corey et al. references would be in possession of the instant claims **because** all references are of analogous art. The references disclose the synthesis of the epoxyester compounds and emphasize their utility as intermediates/precursors for the synthesis of other chiral compounds (see Baures et al. page 6501, Corey et al. (1992) page 6537 and Corey et al. (1991) page 2857, lines 3-4). The prior art references also demonstrate success in synthesizing the optically active epoxyester compounds (see Baures et al., page 6502, Table 2, compound 3a and 3c, Corey et al. (1992), page 6735 and Corey et al. (1991), pages 2857-2858). One having ordinary skill in the art would be motivated to make such modification knowing that reasonable success has been demonstrated

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in analogous compounds. It is prima facie obvious to modify one known compound with attributes proven in analogous compounds.

4. Claims 9, 11 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of U.S. Patent No. 6,787,657 in view of Corey et al. (*Tetrahedron Letters*, 1992, 33, 6735), Corey et al. (*Tetrahedron Letters*, 1991, 32, 2858, Table I and paragraph 4) or Baures et al. (*Tetrahedron Letters*, 1990, 31, 6502). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are drawn to the patented claims when R<sup>2</sup> is a phenyl or tert-butyl group.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

The instant claims 9-11 have a broader scope than claims 1-2 of US 6,787,657. The difference between the instant claims and the patented claims, is that R1 of the instant claimed species can be a methyl, ethyl or a C<sub>3</sub>-C<sub>10</sub> branched, linear or cyclic alkyl group and R<sup>2</sup> is optionally a 4-methoxyphenyl group or a substituted phenyl. Corey et al. disclose a structurally similar compound wherein R<sup>1</sup> is an ethyl group (Tetrahedron Letters, 1992, 33, 6735, see compound 3). Furthermore, Corey et al. disclose a structurally similar compound wherein R<sup>1</sup> is a cyclohexyl and R<sup>2</sup> is a tert-butyl (see *Tetrahedron Letters*, 1991, 32, 2858, Table I and paragraph 4). Finally, Baures et al. disclose a structurally similar compound where R<sup>2</sup> is a 4methoxyphenyl (see Tetrahedron Letters, 1990, 31, 6502, Table 2, compound 3c). One having ordinary skill in the art in possession of the patented claims (US 6,787,657, claims 1-2) and both Corey et al. references and the Baures et al. reference would be in possession of the instant claims because all three of the references are of analogous art. The patented claims and the references disclose the synthesis of the epoxyester compounds and emphasize their usefulness as intermediates for the synthesis of other chiral compounds (see US 6,787,657, column 1, lines 7-11, Baures et al. page 6501, Corey et al. (1992) page 6537 and Corey et al. (1991) Tetrahedron Letters, 32, 2859). The prior art references also demonstrate success in synthesizing the

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optically active epoxyester compounds (see Baures et al., page 6502, Table 2, compound 3c, Corey et al. (1992), page 6735 and Corey et al. (1991), page 2858, paragraph 4). One having ordinary skill in the art would be motivated to make such modification knowing that reasonable success has been demonstrated in analogous compounds. It is prima facie obvious to modify one known compound with *attributes* proven in analogous compounds.

#### Conclusion

### 5. None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Sarah E. Perlinger, whose telephone number is (571) 272-5574. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Cecilia Tsang, can be reached at (571) 272-0562. The fax number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

02/07/2006

Celia Chang Primary Examiner Art Unit 1625